

## **REMARKS**

### **Status of the Claims**

Claims 13-15 and 18-23 were pending for examination, claim 13 being independent.

Claim 24 is withdrawn.

Claims 25 – 31 have been amended.

New claims 32 and 33 have been added.

After the present amendment, claims 13-15 and 18-23 and 25 - 33 are pending for examination, claim 13 being independent.

### **1. Preliminary Comments**

Claim 13 has been amended to clarify that the change in taper is in an outer dimension of the injector. Support for this amendment is given, for example, by FIG. 2.

Support for new claims 32 and 33 is given, for example, by FIGs. 2 and 3, respectively.

Additionally, the Applicants have clarified their arguments in the last paragraph on beginning at the top of page 8 of this document.

### **2. Claims 13-15, 18-23 and 25-30 were improperly rejected under 35 U.S.C. §103(a) over Clark in view of Brown**

#### **A. Discussion of the Cited Prior Art**

Clark discloses an instrument for inserting a flexible intraocular lens into an eye (Abstract, lines 1-2). The instrument includes a compressor for laterally compressing the lens into a small cross-sectional configuration to pass the lens through a narrow incision (Abstract, lines 2-5). The compressor includes retainers along the interior of the inserter to maintain the side edges of the lens in a substantially planar orientation during compression (Abstract, lines 5-8). The free end of the instrument is provided with a pair of opposed longitudinal slits 121 (col. 6, lines 31-33). The slits 121 are wide enough to permit sides of the optic to extend beyond the exterior sides of the cannula 28 (col. 6, lines 33-35). Clark discloses that slits permit lateral expansion of the lens prior to release of the lens into the eye (col. 6, lines 35-36). Clark further discloses that the natural resilient force which biases the lens to assume its original uncompressed shape is dissipated in a controlled environment of the cannula (col. 6, lines 37-39). Clark also discloses that cannula 28 includes a proximal funnel-shaped portion 103 which tapers to compress the lens, and an elongate distal portion 105 which directs the compressed lens into an eye.

As shown in each of FIGS. 2, 3, 11 and 12 of Clark, the slit 121 extends only along distal portion 105 (which has only a single taper), and not along funnel-shaped portion 103.

Brown is directed primarily to an intraocular lens plunger having a blunt, rounded tip that is offset from the center line of the plunger rod (Abstract, lines 1-2). Brown discloses that such a configuration assures that the tip is biased downward against the bottom of the cartridge bores (Abstract 2-4). Brown states that such biasing helps prevent the tip from riding up over the IOL and thereby being folded within the IOL (Abstract, lines 4-6). Brown discloses an injector segments having different taper (e.g., see FIG. 4).

The injector of Brown does not include any slits or slots.

**B. Claims 13-15, 18-23 and 25-30 were improperly rejected under 35 U.S.C.**

**§103(a) over Clark in view of Brown because none of the art of record discloses “[a] slot extending from [an] open end through [a] second segment and [a] third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper” and the Examiner’s rationale for modifying Clark to include such a configuration is insufficient**

The Examiner alleges that Clark discloses all elements of claim 13 except a second segment connected to a third segment at a transition point, the transition point characterized by a discrete change in taper. However, the Examiner alleges that Brown discloses, in FIG. 4, an IOL injector comprising, a tip comprising a third segment having a constant diameter, a second segment having a taper located on the outer surface and a taper located on the inner surface of bore 16. The Examiner further alleges that it would have been obvious to one of ordinary skill in the art to optimize the lengths of slots 121 to extend through the second segment to ensure that the IOL gradually returns to its original shape before being released into the eye to avoid complications of injuring the eye. The Applicants respectfully disagree with some of the Examiner’s allegations and disagree that claim 13 is obvious in view of the cited art.

The Applicants agree that Clark fails to disclose “An injector ... comprising ... at least one slot extending from the open end through the second segment and the third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper.” Furthermore, none of the art of record shows a transition point having a change

in taper, as recited in claim 13. The Applicants further point out that Brown does not disclose a slot of any kind extending from the open end.

Below, the Applicants address the Examiner's allegation that it would have been obvious to one of ordinary skill in the art "to optimize" the lengths of slots (i.e., "slits 121" of Clark) to extend through a second segment of an apparatus formed by a combination of the apparatus of Clark and Brown to ensure that the IOL gradually returns to its original shape before being released into the eye to avoid complications.

The Applicants do not deny slots were known. In fact, even Clark discloses that the slits 121 (i.e., slots) permit lateral expansion of the lens prior to release into the eye (col. 6, lines 35-36). Clark further discloses that, as a result of such expansion, the natural resilience which biases the lens to assume its original uncompressed shape is dissipated in the controlled environment of the cannula (col. 6, lines 37-38 of Clark). However, neither Clark nor Brown discloses "An injector ... comprising ... at least one slot extending from the open end through the second segment and the third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper," as recited in claim 13. In fact Clark shows a slot extending across only a single segment, with no change in taper.

Regarding the Examiner's allegation that it would have been obvious to one of ordinary skill in the art to optimize the lengths of slots 121 to extend through the second segment to ensure that the IOL gradually returns to its original shape before being released into the eye to avoid complications, the Applicants note that none of the art of record suggests such a configuration. Rather, as stated above, Clark discloses a slot that extends into a single segment. Significantly, Clark teaches that such a configuration (without any modification) achieves the result that the Examiner sets forth as the rationale for modifying Clark (i.e., gradual return of the IOL to its original shape before it is released into the eye). Accordingly, the Examiner's rationale for modification is without merit.

Furthermore, the Examiner's allegation that modifying the slot of Clark is "an optimization" is without support from any of the art of record. In fact, as stated above, the Examiner's alleged motivation for modifying the slot of Clark (i.e., to ensure that the IOL gradually returns to its original shape before being released into the eye to avoid complications of injuring the eye) can be achieved with the slot as described in the prior art slit where the slot extends over only a single segment.

Additionally, there is nothing of record that suggests that a reasonable expectation of success exists if the slot is extended from the open end through the second segment and the third segment across a transition point characterized by a change in taper. In fact, in Brown, in the region identified by the Examiner as the second region, the taper of the outer dimension corresponds to a taper of the internal dimensions the taper of the internal dimensions being configured to compress an IOL moving through the injector lumen (see FIG. 4 of Brown and the Examiner's Reply page 4, lines 10-12). There is nothing to suggest that a slot that is formed in the cone-shaped, IOL compression portion would allow the lens to unfold properly. Furthermore, the presence of at least one slot in the cone-shaped, IOL compression portion would defeat the purpose of compression region as the slot would tend to allow the IOL to decompress.

Accordingly, there is no teaching of the modification (i.e., optimization) to Clark as proposed by the Examiner and there is no rationale for making such a modification to Clark. It is worth mentioning that the reason set forth in the Specification of instant application for the slot configuration as recited in claim 1 (i.e., providing a doctor with options for anchoring the tip of the inserter in the eye during injection of a lens" (see page 12, line 13 et seq. of the present application)) is entirely different than any reason set forth in Clark or Brown.

For the above reasons, claim 13 is patentable over the combination of Clark and Brown.

Claims 14, 15 and 18-23, 25-31 depend from claim 13 and are patentable for at least the same reasons as claim 13. Withdrawal of the rejections of claims 13-15, 18-23 and 25-31 is respectfully requested.

**3. Claim 27 was improperly rejected under 35 U.S.C. §103(a) over Clark in view of Brown and further in view of Ott.**

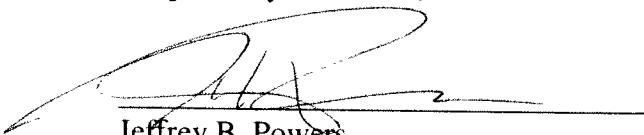
Ott discloses an IOL inserter including a cartridge. The cartridge has segments having different tapers (e.g., see FIG. 4A). Ott does not disclose an inserter having any slots or slits. Ott does not cure the deficiencies of the combination of Clark and Brown as set forth above. Accordingly, claim 27 is patentable over any combination of Clark, Brown and Ott.

It is believed that all claims are now in condition for allowance, early notice of which would be appreciated.

No additional fee is believed to be due. However, please charge any additional fees or credit overpayment to Deposit Account No. 02-1425.

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Respectfully submitted,



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